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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,050	08/06/2003	Kenneth B. Carl	WIC-2630US1	1329
23122	7590	05/19/2004	EXAMINER	
RATNERPRESTIA			BEISNER, WILLIAM H	
P O BOX 980			ART UNIT	
VALLEY FORGE, PA 19482-0980			PAPER NUMBER	

1744

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/635,050

Applicant(s)

CARLL, KENNETH B.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Preliminary Amendments filed 06 Aug. 200.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 26-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06 Aug. 2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed 06 Aug. 2003 has been considered and made of record.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 4, 6, 26, 28, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney (GB 2 202 549) in view of Omasa (US 5,375,926).

The reference of Whitney discloses a pre-sterilized cell culture vessel which includes a headplate and a collapsible bag sealed to an edge of the headplate. The headplate includes at least one port (See Figures 3 and 4).

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While the reference of Whitney discloses the use of a rotating blade impeller with the collapsible bag, the instant claims recite that the impeller is flexible or includes flexible blades and is attached to the headplate such that it does not rotate about its central axis.

The reference of Omasa discloses an impeller construction known in the art which includes flexible blades (4) attached to a shaft (3) which is attached to the headplate (12) of the vessel such that the shaft does not rotate about its central axis (See Figure 10).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an impeller as disclosed by the reference Omasa in place of the impeller of the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, mixing the liquid contents of the vessel while avoiding the drawbacks associated with rotational agitators (See column 1, lines 34-38, of Omasa).

With respect to the material of construction of the impeller recited in claims 6 and 30, the reference of Omasa discloses a number of different materials which can be used as a material of construction (See column 5, lines 13-18). The reference states the use of synthetic resin.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a material of construction of the impeller based merely on design considerations such as the intended use of the device in terms of the liquid which is to be mixed. Use of a well known synthetic material such as polyethylene would have been obvious for the known and expected result of providing a material which is resistance to rust and can be easily molded.

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5. Claims 2, 6, 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitney (GB 2 202 549) in view of Omasa (US 5,375,926) and McCabe et al.(US 5,288,296).

The combination of the references of Whitney and Omasa has been discussed above.

While the reference discloses the use of polypropylene for the construction of the flexible vessel, the reference discloses that other materials can be used. Desirable materials would include materials capable of withstanding sterilization.

The reference of McCabe et al. discloses that it is known in the art to employ polyethylene as a culture vessel material (See column 3, lines 41-59).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the vessel out of polyethylene rather than polypropylene for the known and expected result of providing an alternative means recognized in the art to achieve the same result, construction of the vessel out of a material which is capable of withstanding sterilization.

The same holds true for the material of construction of the impeller blades.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 3, 26 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 18 and 24 of U.S. Patent No. 6,670,171. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 1 and 26 are anticipated by claims 1, 18 and 24 of U.S. Patent No. '171.

Instant claims 3, 4, 28 and 29 are anticipated by claims 7 and 8 of U.S. Patent No. '171.

Instant claims 3 and 28 are anticipated by claims 18 and 24 of U.S. Patent No. '171.

8. Claims 2, 6, 27 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, 8, 18 and 24 of U.S. Patent No. 6,670,171 in view of Omasa (US 5,375,926) and McCabe et al.(US 5,288,296).

Claims 1, 7, 8, 18 and 24 of U.S. Patent No. 6,670,171 have been discussed above.

With respect to the material of construction of the impeller recited in claims 6 and 30, the reference of Omasa discloses a number of different materials which can be used as a material of construction (See column 5, lines 13-18). The reference states the use of synthetic resin.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a material of construction of the impeller based merely on design considerations such as the intended use of the device in terms of the liquid which is to be mixed. Use of a well known synthetic material such as polyethylene would have been obvious for the known and expected result of providing a material which is resistance to rust and can be easily molded.

The reference of McCabe et al. discloses that it is known in the art to employ polyethylene as a culture vessel material (See column 3, lines 41-59).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the vessel out of polyethylene rather than polypropylene for the known and expected result of providing an alternative means recognized in the art to achieve the same result, construction of the vessel out of a material which is capable of withstanding sterilization.


The same holds true for the material of construction of the impeller blades.

### *Conclusion*

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB